K111041 (1/1)

510(k) SUMMARY

JUN - 6 2011

Submitter Information

Submitter's Name:	OrthoHelix Surgical Designs, Inc.
Address:	1065 Medina Rd, Suite 500 Medina, Ohio 44256
Telephone Number:	330-869-9562
Fax Number:	330-247-1598
Prepared By:	Brian Hockett, Liz Altenau
Contact Person:	Derek Lewis
Date Prepared:	4/12/11

Device Information

Trade Name:	Mini Variable System
Common Name:	Fixation Plates and Screws
Classification Name:	Plate, Fixation, Bone
Device Classification:	Single/multiple component metallic bone fixation appliances (Class II per 21 CFR 888.3030) Panel: Orthopedic, Product Code: HRS Smooth or threaded metallic bone fixation fastener (Class II per 21 CFR 888.3040) Panel: Orthopedic, Product Code: HWC
Material Composition:	Titanium Alloy, PEEK
Device Description:	The submission is a modification to the Mini MaxLock Extreme® Plating System and MaxLock Extreme® Distal Radius Plates and Screws to add Mini Variable components. No modifications were made to the existing plates or screws – this addition will be compatible with all plates in the current systems. The OrthoHelix Mini Variable construct consists of a polymer ring which mates with the locking holes in a plate and allows for a specially designed locking screw to be inserted at angles up to 15° in any direction while maintaining angular stability.
Intended Use:	The Mini Variable System, when used with the Mini MaxLock Extreme® Plating System, is intended to stabilize and aid in the repair of fractures, fusions, and osteotomies for small bones and bone fragments. The Mini Variable System, when used with the MaxLock Extreme® Distal Radius Plates and Screws, is intended for fractures and osteotomies of the distal radius in adult patients.
Substantial Equivalence:	The Mini Variable System is substantially equivalent to the OrthoHelix Mini MaxLock Extreme® Plating System Screws (K101962), the OrthoHelix MaxLock Extreme® Distal Radius Screws (K102156), The OrthoHelix MaxLock Extreme® System with Variable Angle Technology (K100618), and the Synthes 2.4mm/2.7mm Variable Angle (VA)-LCP Forefoot/Midfoot System. Calculations and mechanical testing comparing the bending and torsional strength of the subject and predicate devices were performed and the results support substantial equivalence. Due to similarities in indications, design, and materials, no other testing was required. No new issues of safety and effectiveness have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OrthoHelix Surgical Designs, Inc.
% Mr. Derek Lewis
Vice-President of Research and Development
1065 Medina Road, Suite 500
Medina, Ohio 44256

JUN - 6 2011

Re: K111041
Trade/Device Name: Mini Variable System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: May 20, 2011
Received: May 23, 2011

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111041(111)

Indications for Use

510(k) Number (if known):

Device Name: Mini Variable System

Indications for Use:

The Mini Variable System, when used with the Mini MaxLock Extreme® Plating System, is intended to stabilize and aid in the repair of fractures, fusions, and osteotomies for small bones and bone fragments.

The Mini Variable System, when used with the MaxLock Extreme® Distal Radius Plates and Screws, is intended for fractures and osteotomies of the distal radius in adult patients.

Prescription Use ___X___ AND/OR Over-The-Counter-Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111041